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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY
(TRENTON DIVISION)

—X—

ANNETTE WAGNER,

SECOND AMENDED COMPLAINT

Plaintiff,

v.

No. 3:18-cv-10065 ECF CASE
Jury Trial Demanded: Yes

CATALENT PHARMA SOLUTIONS, LLC,

Defendant.

—X—

Plaintiff, **ANNETTE WAGNER**, by and through her undersigned counsel, by way of Complaint against Defendant **CATALENT PHARMA SOLUTIONS, LLC**, seeks relief for violations of laws protecting an employee acting as a whistleblower from unlawful retaliation and under laws protecting a female employee from being subject to gender discrimination in the workplace. In support of her Second Amended Complaint, Plaintiff states as follows:

INTRODUCTION

1. Plaintiff Annette Wagner (“Wagner” or “Plaintiff”) was a productive and well-regarded employee of the Defendant Catalent Pharma Solutions, LLC (“Catalent” or “Defendant”) as a Director of Product Development, reporting directly to the Vice President of Quality Assurance and Regulatory Affairs based in Defendant’s principal place of business in Somerset,

New Jersey. Ms. Wagner, who at all times relevant had a very successful career in the pharmaceutical industry, made disclosures and reported wrongful and unlawful acts at Catalent's drug production facility in Winchester, Kentucky. Following her disclosures and reports, Defendant Catalent's management engaged in a campaign to interfere and stop Plaintiff's disclosures and reports of violations of production practice and safety standards, including the wrongful termination of Ms. Wagner in June 2017. As a result of the unlawful termination of Ms. Wagner, she has suffered loss of pay, benefits, emotional distress and serious damage to her career. Plaintiff brings her claims as a whistleblower subjected to unlawful retaliation in violation of the New Jersey Conscientious Employee Protection Act ("CEPA"), *N.J.S.A. 34:19-1 to -14*, the False Claims Act, 31 U.S.C. § 3730, gender discrimination in violation of the New Jersey Law Against Discrimination ("LAD"), *N.J.S.A. 10:5-1 to -42*, and, in the alternative, for wrongful discharge in violation of public policy under the laws of Kentucky.

JURISDICTION & VENUE

2. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332 because there is complete diversity between the parties in this civil action and damages in this case exceed \$75,000.00, exclusive of interest and costs, and 28 U.S.C. § 1331 because this is a civil action arising under the laws of the United States, including 31 U.S.C. § 3729 *et seq.*, commonly known as the False Claims Act.

3. Venue is proper in this district pursuant to 29 U.S.C. § 1132(e)(2) as some or all wrongful acts occurred in this District and the Defendant may be found in this District.

PARTIES

4. At all times relevant herein, Plaintiff Wagner has been an experienced professional in the pharmaceutical industry, with nearly 30 years of employment in the industry. Plaintiff was

recruited by Defendant Catalent. Plaintiff then began working for the Defendant on or about July 11, 2016, and performed in an exceptional manner for Defendant until her wrongful termination on June 16, 2017.

5. At all times relevant herein, Ms. Wagner worked for Defendant Catalent as Director of Product Development in Defendant's Winchester, Kentucky plant. Ms. Wagner reported directly to Scott Gunther, a Vice President of Quality Assurance and Regulatory Affairs for Defendant Catalent based in the Defendant's Somerset, New Jersey home office.

6. Ms. Wagner is a citizen of the State of Kentucky.

7. Defendant Catalent is a Delaware corporation, with its principal place of business located at 14 Schoolhouse Road, Somerset, New Jersey 08873. Defendant describes itself, inter alia, as "the world's #1 drug development, delivery and supply partner for drugs, biologics and consumer health products . . ."

8. Defendant Catalent is a pharmaceutical company subject to regulation by, inter alia, the United States Government, including the Food and Drug Administration ("FDA") and the Occupational Safety and Health Administration ("OSHA"). Additionally, Defendant Catalent is an employer with thousands of employees worldwide.

FACTUAL ALLEGATIONS

9. Ms. Wagner was recruited by Defendant Catalent and offered employment as the Director of Product Development ("Director") in May 2016. The Director position required Plaintiff to be based in Winchester, Kentucky ("Winchester") facility of Defendant. Additionally, Plaintiff was to report directly to Scott Gunther, a Vice President of Catalent based in New Jersey. A true and exact copy of Plaintiff's offer of employment letter with terms of employment from Defendant is attached hereto as Exhibit A and incorporated herein.

10. As a Director for Defendant, Ms. Wagner's job responsibilities included, inter alia, to be lead and execute the oral solid drug Development Programs at Catalent's Winchester facility including the creation of scientific sound oral solid development concepts while ensuring that compliance with all relevant drug laws, Good Manufacturing Practices (GMP) guidelines and environmental health and safety requirements. The Director position was responsible for, Technology Transfers into the site; strategy for building site Product Development capability and competency, and managing site Product Development Scientists. Additionally, the Director position was responsible for managing the Winchester Kentucky site's deviation investigation team, who investigated and documented nonconformances in the manufacturing processes, determining product impact and corrective actions.

11. At all times relevant herein, Ms. Wagner was a direct report and supervised by Scott Gunther, Catalent's Vice President of Quality Assurance and Regulatory Affairs based in the Defendant's principal place of business in Somerset, New Jersey. Ms. Wagner also reported to Kay Schmidt, a Vice President of Project Management of Defendant and part of the Catalent Executive Management Team directing all operations of Catalent from New Jersey.

12. As a condition of Ms. Wagner's employment with Catalent, she entered into an agreement with Catalent regarding her employment as Director that stated, among other things, the "Agreement was governed by and interpreted in accordance with the laws of the State of New Jersey, without giving effect to conflict of law rules." Accordingly, Ms. Wagner's employment with Catalent was governed by New Jersey laws at the request of Catalent, including New Jersey's laws related to employment. A true and exact copy of Plaintiff's

Catelent Confidentiality Agreement (the "Agreement") is attached hereto as Exhibit B, and incorporated herein.

13. From the start of her employment with Catalent, Ms. Wagner put in long hours, came into work during off shifts to interact with manufacturing employees and became a visible and approachable leader at the Winchester facility.

14. Additionally, to be successful in her position for Defendant, Ms. Wagner relocated her family from Maryland to Winchester, Kentucky based upon her position with Defendant. In fact, Ms. Wagner had closed on a new home in Winchester, Kentucky on the day she learned of her abrupt termination by Defendant.

15. In her position as a Director, Plaintiff was a consistent top performer for Defendant Catalent. For example, Mr. Gunther, Plaintiff's immediate supervisor, routinely praised Ms. Wagner's work ethic, enthusiastic participation in company community service initiatives, management of critical investigations and leadership skills.

16. Additionally, in October 2016, Mr. Jason Luring, Defendant's area head of Human Resources at the Winchester facility, recognized Ms. Wagner for her "effort and commitment to be a visible and engaging leader here in Winchester."

17. Ms. Wagner's superior work performance is also captured in Defendant Catalent's September 2016 Winchester Organizational Inventory ("WOI"). In that analysis, Senior Leadership Team ("SLT") members ranked Ms. Wagner as one of the Winchester facility's best performing Directors. Plaintiff received a rating of "Exceeds" or "Significantly Exceeds" on five out of the six rated categories and was one of only three Directors who did not receive a rating below "Meets" on a rated competency.

18. Ms. Wagner's performance was based upon her expertise in Current Good Manufacturing Practices ("cGMP") manufacture, with over 20 years of experience in the field. Ms. Wagner had been repeatedly recognized for her management skills within the pharmaceutical companies that she had worked, and also had an additional 15 years of research experience and multiple publications.

19. Shortly after being hired by Defendant as a Director, Ms. Wagner detected and reported multiple cGMP violations in the operations of the Winchester facility, including failure to adhere to company standard operating procedures ("SOPs") and policies. For example, Plaintiff detected violations by Defendant and reported them to Defendant's management on a regular basis from shortly after her arrival to the Winchester Facility until her termination in June 2017, including: 1) OTW-QSY-0013, Quality Systems, Structure, Function, and Department Responsibility- ensuring compliance with GMPs and applicable SOPs throughout the facility, which violations were reported by Plaintiff almost daily throughout Plaintiff's employment with Defendant to Ritchie Davis, Interim General Manager and Director of Operations, Chris Abney, Asst Director of Operations, Kristie Lauterbach, QA Director, Scott Gunther, VP Quality, Denis Johnson, General Manager, Jason Luring, Area HR Director as well as members of the Winchester Site Leadership team; 2) OTW-TRN-0003, Employee Training Program- ensure that training programs are established and managed to assure that personnel are qualified with the appropriate skills to perform their job duties, which violations were reported by Plaintiff almost daily throughout Plaintiff's employment with Defendant to Ritchie Davis, Interim General Manager and Director of Operations, Chris Abney, Asst Director of Operations, Kristie Lauterbach, QA Director, Scott Gunther, VP Quality, Denis Johnson, General Manager, Jason Luring, Area HR Director as well as members of the Winchester Site Leadership team; (3) falsification of

documentation SOP violations: OTW-QSY-0033- Investigation of Problem Record (PR) Exception Events- deviation from approved standards, or written instructions must be reported, which violations were reported by Plaintiff in September 2016 to Scott Gunther and Jason Luring as well as Defendant's legal department in New Jersey; and (4) noncompliance with a host of cGMP regulations SOP violations, including: a) SOP OTW-QS-0013- Quality Systems, Structure, Function, and Department Responsibility –assuring corrective actions are implemented to prevent recurrence of nonconformances; and b) SOP OTW-TRN-0003 Employee Training Program- ensuring that the training program is established and managed to ensure personnel are trained adequately prior to performing their assigned tasks, which violations were reported by Plaintiff almost daily throughout Plaintiff's employment with Defendant to Ritchie Davis, Interim General Manager and Director of Operations, Chris Abney, Asst Director of Operations, Kristie Lauterbach, QA Director, Scott Gunther, VP Quality, Denis Johnson, General Manager, Jason Luring, Area HR Director as well as members of the Winchester Site Leadership team.

20. 21 CFR Part 211.22(a), a federal regulation affecting work at the Winchester facility, provides, in pertinent part, that: "There shall be a quality control unit that shall have the responsibility and authority to approve or reject all components, drug product containers, closures, in-process materials, packaging material, labeling, and drug products, and the authority to review production records to assure that no errors have occurred or, if errors have occurred, that they have been fully investigated."

21. 21 CFR Part 211.25(a), a federal regulation affecting work at the Winchester facility, provides, in pertinent part, that: "Each person engaged in the manufacture, processing, packing, or holding of a drug product shall have education, training, and experience, or any combination thereof, to enable that person to perform the assigned functions. Training shall be in

the particular operations that the employee performs and in current good manufacturing practice (including the current good manufacturing practice regulations in this chapter and written procedures required by these regulations) as they relate to the employee's functions. Training in current good manufacturing practice shall be conducted by qualified individuals on a continuing basis and with sufficient frequency to assure that employees remain familiar with CGMP requirements applicable to them."

22. 21 CFR Part 211.100(a)(b), a federal regulation affecting work at the Winchester facility, regarding written procedures and deviations in drug production, provides, in pertinent part, that: "(a) There shall be written procedures for production and process control designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess. Such procedures shall include all requirements in this subpart. These written procedures, including any changes, shall be drafted, reviewed, and approved by the appropriate organizational units and reviewed and approved by the quality control unit. (b) Written production and process control procedures shall be followed in the execution of the various production and process control functions and shall be documented at the time of performance. Any deviation from the written procedures shall be recorded and justified."

23. In 2016 and 2017, Ms. Wagner detected and reported to Defendant's management the Winchester facility's failure to properly train employees engaged in the manufacture of drugs. For example, Plaintiff detected violations, including: (1) SOP OTW-TRN-0003 *Employee Training Program*- ensuring that the training program is established and managed to ensure personnel are trained adequately prior to performing their assigned tasks; (2) OTW-TRN-0004: *Manufacturing Training Program* – manufacturing staff must be trained and training documented prior to performance of their assigned duties as well as violation of CFR Part 211.25(a), which

states in pertinent part that: “Each person engaged in the manufacture, processing, packing, or holding of a drug product shall have education, training, and experience, or any combination thereof, to enable that person to perform the assigned functions. Training shall be in the particular operations that the employee performs and in current good manufacturing practice (including the current good manufacturing practice regulations in this chapter and written procedures required by these regulations) as they relate to the employee's functions. Training in current good manufacturing practice shall be conducted by qualified individuals on a continuing basis and with sufficient frequency to assure that employees remain familiar with cGMP requirements applicable to them.”

24. Ms. Wagner's investigation into the violation issues set forth in this Complaint led to a determination that Defendant's management had knowledge of the Winchester facility's failure to train its employees, yet for several years took no meaningful corrective action. Plaintiff identified the failure to train issue throughout her employment, including during internal audit reviews and discussions with Quality Assurance (“QA”) Manager Kris Burchette and during internal audit review meeting in November 2016, where over 15 management staff for Defendant were present, including other Directors, such as Mike Broaddus, Director of Commercial Operations, Sunil Nair, Director of Supply Chain, Larry Lawless, Director of Project Management, and Chris Abney, Associate Director of Operations, who each reported to the Catalent Executive Management team in New Jersey. Plaintiff brought up the noncompliance with regulations and rules at the meeting and asked for an explanation. Ms. Burchette stated that the training problem had been identified during internal audits for several years, but that no one had taken action to correct it.

25. The violations Ms. Burchett acknowledged to Plaintiff include violations of: (1) SOP OTW-TRN-0003 Employee Training Program- ensuring that the training program is established and managed to ensure personnel are trained adequately prior to performing their assigned tasks; (2) OTW-TRN-0004: Manufacturing Training Program – manufacturing staff must be trained and training documented prior to performance of their assigned duties; and (3) OTW-QSY-0025, Internal Audits: Identified internal audit observations must have corrective and preventive actions documented and implemented to ensure that the issues do not reoccur. Furthermore, the acknowledged violations create a violation of 21 CFR Part 211.25(a), which requires personnel to have certain qualifications.

26. Another recurring issue Ms. Wagner discovered in Defendant's site, involved the preparation of deviation investigation reports in violation of Defendant Catalent's SOP requirements. As part of Plaintiff's duties she reviewed her staff member's deviation reports prior to submission to the client for approval. Plaintiff found that her employees and other site staff were routinely ignoring the requirements of deviation SOPs required by the CFR. For example, in SOP OTW-QSY-0033 there was a list of documents and information that were to be reviewed and documented as part of an investigation, but this was routinely being ignored resulting in incomplete and inaccurate investigation reports.

27. Additionally, Defendant's QA manager Brian Lane and his staff were responsible for reviewing investigation reports prior to submission to the client for approval and it was admitted by Mr. Lane and his employee that they did not review the reports against the SOP requirements nor did they ensure that the data/conclusions submitted in the report were factual or accurate. Plaintiff reported this situation to Kristie Lauterbach (head of QA), Mr. Gunther and other site leaders, however no action was taken to have QA perform their job duties per SOP OTW-

QSY-0033 and no disciplinary action was taken against Mr. Lane or his staff. This was also a violation of the requirements of the CFR.

28. Additional, on or about December, 2017, Ms. Wagner notified by email the Winchester General Manager Denis Johnson, Mr. Gunther, Winchester interim Director of Operations Chris Abney, and Winchester facility Safety Officer Brandon McDaniel of her concerns for the safety of Defendant's workers because the active pharmaceutical ingredient (API) Nitazoxanide for the drug Alinia manufactured for customer Romark at the Winchester facility. The API was staining the skin and clothing of workers and was being tracked into the hallways of the facility as well as the workers' personal property outside of the manufacturing facility. This situation created an exposure risk to Defendant's employees and a potential contamination risk to other drug products being made at the Winchester facility at the same time.

29. Despite Ms. Wagner's communications to Defendant's management about safety concerns, including speaking directly to Mr. Gunther and Safety Officer McDaniel in early January 2017, no response was provided to Plaintiff or action taken by Defendant to correct the safety issues. The product causing these safety problems had been made in the Winchester facility for over 6 years, and the safety issue had never been addressed. According to Nitazoxanide's Material Safety Data Sheet (MSDS), the chemical is irritating to eyes, skin, and mucous membranes, and upper respiratory tract. Workers should avoid contact and inhalation, and wear the appropriate personal protective equipment, including compatible chemical resistant gloves. Production by Defendant using Nitazoxanide continued, however, with no change in the safety practices. The said production created SOP violations, including of OTW-SAF-0025 *General Safety Rules/Work Practices*- which requires an employer to provide employees with a place of employment that is free from recognized hazards.

30. Moreover, Ms. Wagner's attempt to understand and document the scope of the cGMP training violations in Catalent's Winchester facility were met with hostility and resistance by Defendant. For example, in 2016, Catalent's Winchester facility Quality Assurance Director, Ms. Lauterbach, accused Ms. Wagner of conducting a "witch hunt." Additionally, Mr. Luring, the Defendant's Area Human Resources Director, told Ms. Wagner that there was too much turmoil at the Winchester facility for her to move forward with a formal complaint about training compliance violations.

31. On another occasion, in 2016, Mr. Gunther advised Ms. Wagner to ignore cGMP and SOP violations at the Winchester facility and not document them within the company's Trackwise system. In the course of investigating a manufacturing deviation, Ms. Wagner found that the Catalent SOP for maintenance of tablet tooling sets specifically used for Romark's Alinia (Nitazoxanide) tablets had not been followed for several years. Ms. Wagner reported this violation to the interim Director of Operations, Chris Abney, who stated that the tooling set maintenance SOP had only been in effect a couple years and that his team had not gotten around to implementing it for the Romark tablet tooling sets. When Ms. Wagner reported the lack of compliance to Mr. Gunther, he asked her not to document it within the Trackwise system or report it to the client, Romark, as it would complicate the current investigation Ms. Wagner was conducting surrounding production problems with Romark's tablets. Ms. Wagner then discussed this issue with Ms. Kay Schmidt, Vice President of Catalent's Global Project Management and part of Catalent's Executive management Team operating out of New Jersey, her supervisor at the time, explaining her uneasiness with Mr. Gunther and Mr. Abney's responses, as these responses were in direct violation of GMPs and Catalent SOPs. In particular, the following SOPs were among those violated in this situation: (1) OTW-QSY-0029: *Trackwise: Corrective and Preventive Action*; (2)

OTW-QSY-0033: *Investigation of PR Exception Events* any product quality issue or failure and deviation from approved standards, specifications, tolerances or written instructions must be investigated, documented, evaluated and reported; (3) CPS-GQP-8500: *Deviation Management*; and (4) CPS-QP-1155: CAPA Corporate Quality Procedures.

32. Due to the ongoing and persistent training problems that allowed untrained employees to manufacture drugs for Defendant, Ms. Wagner internally raised concerns that Catalent's Winchester facility had knowingly manufactured drugs in violation of cGMPs—which rendered them adulterated—coupled with the reality that some of those drug products were necessarily sold to the federal government, such as the anti-viral drug Tecovirimat.

33. Defendant Catalent's failure to comply with the federal regulations covering the manufacture of medicines, violated FDA laws and regulations. As Ms. Wagner continued to uncover more of such violation issues, Ms. Wagner's role at the Winchester facility was restricted by Defendant so she would have less opportunity to identify these issues.

34. For example, Ms. Wagner was initially told by Defendant that she would be responsible for the PD scientists, investigation team, process development technical specialists and the batch record writing team. As Ms. Wagner identified more compliance issues, Defendant removed the investigation team from her oversight, and Plaintiff was unable to hire to fill vacant positions on the investigation team. The process development technical specialist and batch record writing teams were never moved under Ms. Wagner's oversight as originally determined, even after multiple attempts to move the process forward. In particular, the Interim Director of Operations repeatedly stalled moving his staff under Ms. Wagner's direction, provided roadblocks, and through his own actions, allowed his staff to obstruct investigations by not requiring responses to investigation requests in a timely fashion.

35. Ms. Wagner discovered and reported to Defendant's management that Defendant Catalent allowed employees to manufacture drugs without the appropriate training, that Defendant's employees were not following standard operating procedures, and that Defendant Catalent was intentionally hiding non-conformances that could affect product quality from their customers. All of these are serious violations of FDA regulations and cGMPs that govern drug manufacture. Additionally, the SOP violations that resulted, included: (1) OTW-QSY-0025, *Internal Audits*; (2) OTW-QSY-0029, *Trackwise: Corrective and Preventive Action*; (3) CPS-GQP-1155, *CAPA Corporate Quality Procedure*; (4) CPS-GQP-8500, *Deviation Management*; (5) OTW-QSY-0033, *Investigation of PR Exception Events*; (6) OTW-TRN-0003, *Employee Training Program*; (7) OTW-TRN-0004, *Manufacturing Training Program*; (8) OTW-QSY-0013, *Quality Systems, Structure, Function and Department Responsibilities*; (9) OTW-SAF-0040, *Safety Management*; and (10) OTW-SAF-0025, *General Safety Rules/ Work Practices*.

36. Ms. Wagner was terminated by Defendant on June 16, 2017.

37. Ms. Wagner was told by Defendant that the reasons for her termination were the result of a layoff due to a restructuring in the Project Development/ Project Management division in order to cut costs. However, Larry Lawless, the Director of Project Management, and Plaintiff belonged to this same division and reported to the same supervisor, Kay Schmidt. Mr. Lawless was not terminated by Defendant.

38. The termination of Ms. Wagner by Defendant was not due to a layoff. Instead, Ms. Wagner was allegedly laid off despite the fact that several other managers received significantly worse across-the-board ratings than Ms. Wagner, most notably Larry Lawless. Lawless received a rating of either "Does not Meet" or "Mostly Meets" for six out of the nine total categories for which

he received ratings. Mr. Lawless received no "Exceeds" or "Significantly Exceeds" ratings. Furthermore, Ms. Wagner's SLT composite score of 6.6 was a full point higher than average, where Mr. Lawless' score of 3.1 was 2.5 points lower and consistently ranked at or near the bottom in every category.

39. Additionally, subsequent to Plaintiff's termination, Defendant has advertised an opening for the position Plaintiff held at the Winchester facility.

40. All conditions precedent to the filing of this lawsuit have been met, have been satisfied or have been waived.

COUNT I
(Retaliation in Violation of the New Jersey Conscientious Employee Protection Act)

41. Plaintiff incorporates by reference and realleges each and every allegation contained in paragraphs 1-40 of this Amended Complaint with the same force and vigor as if set out here in full.

42. The CEPA provides, in relevant part, that an employer may not take retaliatory personnel action against an employee objects to, or refuses to participate in any activity, policy or practice which the employee reasonably believes is in violation of a law, or a rule or regulation promulgated pursuant to law, or is fraudulent or criminal, including any activity, policy or practice of deception or misrepresentation which the employee reasonably believes may defraud others; or is incompatible with a clear mandate of public policy concerning the public health, safety or welfare.

43. Additionally, the CEPA provides, in pertinent part, protection of an employee that discloses, or threatens to disclose to a supervisor or to a public body an activity, policy or practice of the employer that the employee reasonably believes is in violation of a law, or a rule or regulation promulgated pursuant to law, including any violation involving deception of, or

misrepresentation to, any shareholder, investor, client, patient, customer, employee, former employee, retiree or pensioner of the employer or any governmental entity, or, in the case of an employee who is a licensed or certified health care professional, reasonably believes constitutes improper quality of patient care; or is fraudulent or criminal, including any activity, policy or practice of deception or misrepresentation which the employee reasonably believes may defraud any shareholder, investor, client, patient, customer, employee, former employee, retiree or pensioner of the employer or any governmental entity.

44. Plaintiff Wagner is an “employee” as defined under the CEPA.

45. Defendant Catalent is an “employer” of Plaintiff as defined under the CEPA.

46. As described above, Plaintiff objected to, and reported to her supervisors Defendant’s serious violations of law, rule or regulation, including but not limited to the issues surrounding the manufacture of drugs at Defendant’s Winchester facility.

47. Information that Plaintiff obtained and objected to as set forth herein was subject to the Agreement Plaintiff signed as a condition of employment with Defendant. The Agreement provided, in pertinent part, that “Confidential Information” “refers to all information related to the business of [Catalent] communicated, learned or generated by Employee . . . “ and that “Employee will not use any Confidential Information in any manner other than for furthering the business of [Catalent].” *See Exhibit B.*

48. The Agreement further provides that “the provisions of this Agreement are a condition of employment with [Catalent], and that employment with [Catalent] and the payment of Employee’s compensation are induced by and in consideration of Employee’s agreement to such provisions and Employee’s acknowledgement of the obligation contained herein.” Finally,

the Agreement provided that the Agreement would be “governed by and interpreted in accordance with the laws of the State of New Jersey, without giving effect to conflict of law rules.”

49. Defendant’s conduct constituted unlawful retaliatory action against Plaintiff as described here is in violation of the CEPA, including Plaintiff’s termination on June 16, 2017. This retaliation by Defendant was a result of, *inter alia*, Plaintiff’s use of Confidential Information to object to, and reported to her supervisors Defendant’s serious violations of law, rule or regulation, including but not limited to the issues surrounding the manufacture of drugs at Defendant’s Winchester facility.

50. The laws, rules or regulations violated by Defendant as set forth herein are within the meaning the CEPA.

51. At all times relevant herein, Plaintiff reasonably believed that Defendant’s acts were violations of laws, rules or regulations and she objected to, and refused to participate in, Defendant’s activities, policies and practices alleged herein.

52. Defendant took retaliatory action against Plaintiff, including but not limited to termination of employment, because Plaintiff objected to, and refused to participate in, Defendant’s activities, policies and practices alleged herein that are in violation of the CEPA.

53. As a direct and proximate result of the unlawful retaliatory actions of Defendant, Plaintiff Wagner has suffered and will continue to suffer damages, including lost wages, benefits and entitlements, damage to her career and reputation, personal humiliation, mental anguish, and embarrassment.

COUNT II
(Retaliation in Violation of 31 U.S.C. § 3730(H))

54. Plaintiff incorporates by reference and realleges each and every allegation

contained in the paragraphs of this Amended Complaint with the same force and vigor as if set out here in full.

55. Plaintiff Wagner engaged in actions protected by the False Claims Act, 31 U.S.C. § 3730, including when she complained about and/or objected to unlawful acts of Defendant as set forth above as well as attempting to stop violations of the False Claims Act and her reporting of such improper acts.

56. At all times relevant herein, various drug products made by Defendant, about which Plaintiff Wagner made disclosures and reported wrongful and unlawful acts at Catalent's drug production facility in Winchester, Kentucky as set forth in this Amended Complaint, were necessarily sold to the federal government, such as the anti-viral drug Tecovirimat which was solely made for sale to the federal government, or drugs sold to the Department of Veterans Affairs such as "Alinia" for Romark Laboratories; "Linzess" for Allergan USA, Inc.; "Nexium" for AstraZeneca; "Esbriet" for Genentech USA; "Methylphenidate" for Mayne Pharma, Inc.; "Cleocin" and "Colestid" for Pfizer, Inc.; "Trokendi XR" and "Oxtellar XR" for Supernus Pharmaceutical; "Qudexy XR", Amantadine" and "Topiramate" for Upsher-Smith Laboratories; and "Lucemyra" for US WorldMeds, LLC.

57. At all times relevant herein, Plaintiff Wagner believed in good faith, and a reasonable employee in the same or similar circumstances as Plaintiff Wagner might believe, that Catalent was committing fraud against the government by virtue of various wrongful and unlawful acts at Catalent's drug production facility in Winchester, Kentucky.

58. At all times relevant herein, Plaintiff Wagner made clear to Defendant that she expected Catalent to stop its deceptive practices and repeatedly informed Catalent that its practices were in violation of FDA regulations. Catalent, being overdue at the time for an FDA

audit of the facility, appeared to perceive Plaintiff Wagner's complaints of violations of FDA regulations as a threat by her to report to the FDA such violations. Thereafter, Plaintiff Wagner was told, *inter alia*, she was engaged in a "witch hunt" and was moved away from responsibilities of her position when she discussed drug production problems on multiple occasions. The specific drugs being produced at the Winchester Facility for sale to the federal government, including the Department of Veterans Affairs, were the anti-viral drug Tecovirimat, and "Alinia" for Romark Laboratories; "Linzess" for Allergan USA, Inc.; "Nexium" for AstraZeneca; "Esbriet" for Genentech USA; "Methylphenidate" for Mayne Pharma, Inc.; "Cleocin" and "Colestid" for Pfizer, Inc.; "Trokendi XR" and "Oxtellar XR" for Supernus Pharmaceutical; "Qudexy XR", Amantadine" and "Topiramate" for Upsher-Smith Laboratories; and "Lucemyra" for US WorldMeds, LLC. As a producer of such drugs, Defendant was reasonably on notice of the distinct possibility of False Claims Act litigation or claims as a result of the reporting by Plaintiff of violations in the manufacturing process of Defendant at the Winchester Facility that would cause economic loss ultimately to the federal government.

59. Plaintiff Wagner explicitly complained to Catalent management that Catalent was violating FDA regulations in order to sell its drugs. Such products manufactured by Catalent would be sold by its customers to, among others, the federal government, notwithstanding their lack of compliance with regulatory requirements. Moreover, after her complaints to Catalent management, Plaintiff Wagner was circumvented, excluded from the regulatory review process in which she was meant to take part, and was told certain regulatory compliance actions were not in her job description. Nevertheless, Plaintiff Wagner had conversations with Catalent management outside the facility and upper management level in New Jersey regarding her concerns.

60. Plaintiff Wagner further engaged in actions protected by the False Claims Act when she complained and/or objected to Defendant's agents about differential treatment, including her treatment of being sidelined from job responsibilities in the workplace as well as refusing to allow Plaintiff Wagner to file a formal complaint with Human Resources about the "witch hunt" comment and not allowing Plaintiff to review additional documents to further determine the extent of violations by Catalent, based upon having been a whistleblower about wrongful acts of Defendant under the False Claims Act.

61. Because of Plaintiff Wagner's protected actions, Defendant retaliated against Plaintiff by, among other things, treating her differently in the workplace and terminating her employment.

62. The acts and omissions committed by Defendant against Plaintiff were willful, malicious and in reckless disregard of Plaintiff's federally protected rights.

63. As a direct and proximate result of Defendant's retaliatory actions, Plaintiff Wagner has suffered and will continue to suffer damages, including lost wages, benefits and entitlements, damage to her career and reputation, personal humiliation, mental anguish, and embarrassment.

COUNT III
(Violations of the Law Against Discrimination (LAD), N.J.S.A. 10:5-1 to -42)-
Discrimination/Disparate Treatment Based on Gender)

64. Plaintiff incorporates by reference herein and realleges the allegations in paragraphs 1-53 of this Amended Complaint with the same force and vigor as if set out here in full.

65. Plaintiff Wagner is female and was qualified for and/or satisfied the minimum qualifications of her position with Defendant.

66. Defendant treated Plaintiff differently than similarly situated male employees by terminating her employment and otherwise treating her differently in the terms and conditions of her employment despite her being qualified, or more qualified, than similarly situated male employees.

67. During Plaintiff's tenure with Defendant at the Winchester facility, derogatory comments about women were frequent. Male employees like the Associate Director of Operations and his staff would make comments about female employees' attire, sexual preference, and comments of a sexual nature about female staff members. Plaintiff also heard a comment made about a female employee's attire when she wore a short skirt and a male employee wondered where she was going after work and the other male employees laughed.

68. Additionally, Plaintiff was aware that a female equipment room employee, Billie Colby, had brought complaints to Jason Luring (HR Director) several times because female employees were called "honey", sweetheart", "baby", etc. by male staff and male supervisors, which were not investigated nor did the work place environment change.

69. Plaintiff discharged her job duties in an effective manner for Defendant and received consistent praise from supervisors and colleagues. For example, Scott Gunther, Plaintiff's immediate supervisor through mid-December 2016, routinely praised her work ethic, enthusiastic participation in company community service initiatives, management of critical investigations and leadership skills.

70. Plaintiff also had higher rankings for job evaluations than male comparators such as Mr. Lawless, a male director located at the Winchester facility.

71. Plaintiff regularly interacted with Defendant's management personnel in the home office in Somerset, New Jersey regarding her position and concerns regarding the Winchester

facility.

72. Despite Plaintiff's superior performance in comparison with Mr. Lawless and others, Plaintiff was terminated from the workplace by Defendant. However, Mr. Lawless was not terminated at that time. Defendant treated its male Director Mr. Lawless more favorably than Plaintiff has been treated with regard to employment.

73. The acts and omissions committed by Defendant were willful, malicious and in reckless disregard of Plaintiff's protected civil rights.

74. As a direct and proximate result of Defendant's discriminatory actions in violation of the LAD, Plaintiff Wagner has suffered and will continue to suffer damages, including lost wages, benefits and entitlements, damage to her career and reputation, personal humiliation, mental anguish, and embarrassment.

COUNT IV
(Wrongful Discharge in Violation of Public Policy under Kentucky Law)

75. Plaintiff incorporates by reference and realleges each and every allegation contained in paragraphs 1-40 of this Amended Complaint with the same force and vigor as if set out here in full.

76. Plaintiff was discharged from Defendant Catalent contrary to the fundamental and well-defined public policy as evidenced by the existing law of the State of Kentucky. In particular, Kentucky law makes unlawful falsifying business records when, with intent to defraud. Ky. Rev. Stat. § 517.050.

77. As described above, Plaintiff objected to, and reported to her supervisors, the General Manager of Winchester Plant and the Catalent HR Department, Defendant's serious violations of law, rule or regulation, including but not limited to the falsifying of business records surrounding the manufacture of drugs at Defendant's Winchester facility. For example,

Plaintiff determined that Bryan Abney, one of her employees, was falsifying documentation in the investigation report for the manufacture of certain pharmaceutical product for a client in Defendant's Winchester, Kentucky facility. Plaintiff tried to terminate Mr. Abney over this falsification issue and wrote up a detailed explanation and investigative report of his falsification activities. When Plaintiff presented the information to her supervisor, Mr Scott Gunther, VP Quality, and Jason Luring, Area HR Director, in or around September 2016, it was raised that Mr. Abney had brought up quality issues concerning a client to the previous General Manager, Steve Havel and the QA Director, Kristie Lauterbach, and had been ignored. He also had just received a very bad performance review from Mr. Havel, which he rebutted, making him disgruntled with his current work situation. Instead of carrying out a termination of Mr. Abney, Defendant attempted to avoid Mr. Abney becoming a "whistleblower" because of his prior reports. Plaintiff's attempt to terminate Mr. Abney was therefore rebuffed and Mr. Abney's investigation report was renamed a "draft." As a result of Plaintiff's investigation into Mr. Abney's falsification of business records, Plaintiff also became aware of deficiencies in the work Defendant's QA manager Brain Lane and his staff at the Winchester Facility, which were violations of the requirements of law and regulations as set forth, *inter alia*, in paragraph 27 herein. As a result of the forgoing, Plaintiff was instructed to violate the law by Defendant by not correcting the situation in the Winchester Facility that allowed for non-compliance of standards such as the falsification of records, lack of proper and documented training of staff, and reporting of non-conformances.

78. Defendant's conduct constituted unlawful retaliatory action against Plaintiff as described herein is in violation of the public policy of the State of Kentucky, including Plaintiff's termination on June 16, 2017.

79. As a direct and proximate result of the unlawful retaliatory actions of Defendant, Plaintiff Wagner has suffered and will continue to suffer damages, including lost wages, benefits and entitlements, damage to her career and reputation, personal humiliation, mental anguish, and embarrassment.

WHEREFORE, Plaintiff Annette Wagner respectfully requests that this Honorable Court grant the following relief:

- (A) Enter judgment on behalf of Plaintiff against Defendant on all counts herein;
- (B) Award Plaintiff reinstatement and other injunctive relief due to Defendant's wrongful termination of her employment plus pre- and post- judgment interest;
- (C) Award compensatory damages to Plaintiff, including for mental and emotional distress, mental pain and suffering, humiliation, loss of dignity, loss of enjoyment of life, expenses, damage to her career and reputation;
- (D) Award Plaintiff punitive damages for Defendant's willful violations;
- (E) Award to Plaintiff reasonable attorneys' fees, costs of suit, all litigation costs allowable, and pre-judgment and post-judgment interest; and
- (F) Grant such other relief to Plaintiff as this Court may deem fair and just.

REQUEST FOR JURY TRIAL

Plaintiff demands a trial by jury on all issues so triable.

Dated: May 17, 2019

Respectfully submitted,

/s/ Neil L. Henrichsen

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CERTIFICATE OF SERVICE

I hereby certify that on this 17th day of May 2019, I electronically filed the foregoing with the clerk of the court by using the CM/ECF system, which provided electronic service upon:

Kristine J. Feher, Esq.
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s/Neil L. Henrichsen
Neil L. Henrichsen